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(54) Intravascular radially expandable stent and method of use.

(57) A radially expandable vascular stent of the type formed of wire wound generally in a helix. Bends are provided in the wire outside its helical path which straightens as the stent is expanded. The stent preferably is made of a low memory metal such as copper alloy, titanium, or gold, and provides a radial support from within a blood vessel after implantation therein. The stent is adapted to act as a permanent prosthesis to assure vascular patency.

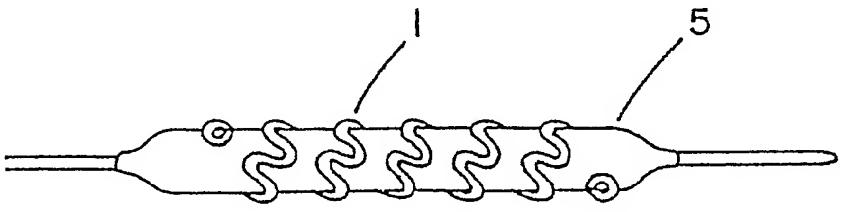

FIG. 2

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This invention relates to a radially expandable vascular stent of the type formed of wire wound generally in a helix.

In US-A-4 649 992 a device is described in combination with a catheter which is basically a compression spring retained between a partially inflated balloon and an abuttment immediately behind the balloon on the catheter shaft. The intent is to transport the spring prosthesis in this manner to the desired location and then after a successful angioplasty procedure release said spring prosthesis by totally evacuating said balloon, thus allowing said spring prosthesis to expand linearly and stay in place while the balloon catheter is withdrawn. This method is quite simple and its simplicity is very attractive; however it has some drawbacks. One an and foremost is the fact that the spring has a fixed diameter and as such is unable to fully conform to the inside wall of the vessel which at times is quite tortuous and thus could conceivably create a somewhat turbulant flow of blood, and possible thrombosis could in some cases result. Other patents, e.g. US-A-4 553 545, teach a different design where a relatively complex mechanical rotating device and co-axial cables are employed to achieve the necessary means to change the diameter of the implanted stent to a larger dimension at the point of implant. Still other patents, e. g. US-A-3 868 956, describe a design wherein a temperature responsive metallic device is used and expanded after implant using external heat sources. All of the above mentioned devices present drawbacks of various magnitudes including blood coagulation and possible thrombosis, and considerable complexity of procedure.

Other reference publications are:

1. "Self-expanding metallic stents for small vessels", Radiology 1987 - 162.469-472.

2. "Flexible balloon-expandable stent for small vessels", Radiology January 1987.

3. "Intravascular stents to prevent occlusion and restenosis after transluminar angioplasty", N.E. J. of M. March 19, 1 987.

4. US-A-4 580 568 "Percutaneous endovascular stent".

5. US-A-4 503 569 "Transluminarely placed expandable graft prosthesis".

6. US-A-4 649 992 "Catheter arrangement having a variable diameter tip and spring prosthesis".

7. US-A-4 681 110 "Catheter arrangement and blood vessel liner".

All of the above references describe and teach various methods of providing or otherwise offering and introducing stents of different types and designs for applications similar to the one described herein in this invention.

A major object of this invention is the provision of a radially expandable stent which generally retains the number of coils and the longitudinal dimension.

In conformity with the present invention a radially expandable vascular stent of the type formed of wire wound generally in a helix, is characterized by bends in the wire outside its helical path which straightens as the stent is expanded.

In the stent of the present invention the bends preferably define a continuous wire formed flat band which is wound on the flat into said helix. The bends may be defined by a zig-zag pattern which is oriented longitudinally with respect to the axis. The helix may be of cylindrical shape, and preferably both ends of the wire are curled into full loops. Most preferably the wire wound helix has the low memory level of a softer than spring type metal used for the wire. Particularly useful wire materials are copper alloys, surgical grade stainless steel, biologically compatible titanium and gold having a purity of at least 18 K.

In conformity with further developments of the present invention the unexpanded stent has an outside diameter equal to or less than 1.9 mm (.075 inch) and is readily expandable to approximately three times its original diameter.

The stent may be combined with means within the wire winding for expanding the winding, particularly an expandable balloon extending longitudinally within the preformed wire winding which preferably is tightly fitted and sized to firmly grip the balloon.

The stent of the present invention is suitable as an intravascular implant for maintaining vascular patency in humans and animals. In its preferred embodiment it comprises an open-ended wire formed device of basically cylindrical shape and made of a softer than spring type metal and fitted over an inflatable element of a typical balloon type catheter such as described in US-A-4 195 637 and US-A-4 402 307. The wire formed device is intended to act as a permanent prosthesis stent and is implanted transluminarely. Specifically this invention is characterized by the ability of said intravascular stent to be enlarged radially after having been introduced percutaneously, transported transluminarely and positioned at desired location. The stent of the invention is particularly useful in transluminar stent implantation in the field of cardiology and especially in the case of coronary angioplasty to prevent restenosis.

An important improvement of this invention over other similar devices such as cited in the patents above, and specifically the device described in US-A-4 649 992, is the ability of the device of this invention to allow for and to maintain a very low profile and a small frontal area, so very

important for purposes of percutaneous insertion. Thus the stent of this invention can be inserted into and be transported via a standard #8F Guiding Catheter such as USCI Cat.# 006128, while using standard procedures and methods. Once on location, the stent can be expanded radially to a diameter larger than initially introduced; a ratio of 2 1/2 : 1 can easily be achieved with a wire diameter of 0.2 mm (.008") and initial stent diameter of 1.9 mm (.075"). The expanded larger diameter will conform to the inside of the vessel and maintain intimate contact with the inside wall. The stent of this invention is characterized by the low memory level of the relatively easily deformable metal used for the wire.

A controlled radial expansion of the stent is accomplished by the force generated by the inflating balloon. When acted upon by the inflating balloon, the stent of this invention comprising the zig-zag preformed wire band subsequently formed into an open-ended cylindrical shape, is by design and intent capable to expand radially.

The radial expansion in effect is achieved by controlled deformation and tension applied to the sinusoidal pattern of the preformed wire band. The low memory metal used for the fabrication of the wire formed stent assures, that the radially expanded stent stays expanded thus fulfilling its primary intent and function.

Other advantages of this invention over the devices mentioned earlier are the inherent post-expansion radial rigidity and linear flexibility, an excellent combination for an intravasuclar and especially intracoronary stent, in the case of intracoronary application an overriding factor being the ability of allowing for an extremely low profile and a very small frontal area so very essential for initial transluminar introduction and transportation through a catheter, e.g. a standard 8F guiding catheter.

The preformed flexible wire stent of this invention allows easy radial expansion and subsequent retention of the radially expanded shape well anchored within a vessel. Still another advantage of this stent is the simplicity of its application, especially with respect to angioplasty, where one procedure accomplishes to distinct functions: in combination with the balloon it compresses the plaque, thus creating a recannalized lumen as characterized by angioplasty, and deploys and implants a permanent prosthesis within the newly created and recannalized lumen to prevent possible reclosure and restenosis thus allowing free flow of blood indefinitely. Both functions are performed simultaneously and with a single insertion of the catheter.

In angioplasty procedures at this time, in many cases restenosis occurs soon thereafter, which requires a secondary procedure or a surgical bypass operation. The implanted prosthesis as described herein will preclude such additional procedures and will maintain vascular patency indefinitely.

Depending on the size used, the stent according to this invention can also be efficacious in other similar applications, such as: repairs of aneurysms, support of artificial vessels or liners of vessels, initial repairs of dissections and mechanical support to prevent collapsing of dilated vessels. Still many other and similar applications will be satisfied by this invention without departing from the basic premise and concept.

This stent particularly allows a single procedure to combine the essential angioplasty and a simultaneous implant of a permanent prosthesis designed and intended to prevent restenosis and further complications arising therefrom, also reducing the risk factor and trauma for the patient.

An exemplary embodiment of the invention will now be described with reference to the accompanying drawings, in which:

Fig. 1 is a side elevation of a preferred embodiment of a stent according to this invention being wound on a mandrel;

Fig. 2 is a side elevation showing an overall view of a stent prosthesis fitted over a deflated balloon;

Fig. 3 shows the balloon and stent assembly advanced within a vessel, approaching a partial occlusion;

Fig. 4 is similar to Fig. 3 showing the balloon and stent assembly inside a partially occluded vessel;

Fig. 5 is similar to Fig. 4, the balloon inflated, and the stent radially expanded, illustrating the preferred method of an angioplasty procedure coupled with a simultaneous deployment and implantation of a permanent prosthesis stent; and

Fig. 6 is a view similar to Fig. 5 showing the prosthesis stent implanted and plaque compressed and retained after removal of the balloon.

For purposes of better and clearer understanding of this invention reference is made to Figs. 1 - 6. The preferred embodiment of this invention is shown and described in an application for angioplasty; however, it is understood that other applications not specifically mentioned herein are possible and no limitations in scope of this invention are intended or implied without departing from the basic principles of this invention.

Fig. 1 shows the details of construction of a prosthesis stent 1, hereafter called stent, which is basically of a hollow open-ended cylindrical shape. The configuration of stent 1, illustrated in Fig. 1, is such, that a wire 2 is initially preformed into a two-dimensional zig-zag form 3, basically creating a flat expandable band 3A. The zig-zag pattern can vary

as to its shape and tightness of the reversing bends, but for reasons of simple description a typical sinusoidal form is chosen to depict this band's construction.

In order to create the stent 1, and to have it assume an initial tubular configuration as shown in Fig. 1, also a subsequently radially expanded condition as shown in Fig. 5, a length of preformed wire band 3A is wrapped on a suitable mandrel 4 in a manner similar to that of winding a simple helical spring again as shown in Fig. 1. Care is taken to form the wire band 3A flat around the mandrel 4 with little or no tension to prevent premature linear expansion of band 3A.

Once the zig-zag band 3A is wound into a cylindrical shape, it is removed from the mandrel 4, and is placed over a suitable variable diameter device such as an inflatable balloon 5 typically used for angioplasty procedures as shown in Fig. 2. A suitable forming tool (not shown) is used to tighten the stent over the balloon; manual operation of squeezing the stent over the balloon is also acceptable.

The wire is made of drawn low-memory level material such as stainless steel, titanium ASTM F-63-83 Grade 1 or high carat gold K 19-22. A copper alloy typically 110, when properly coated with polyester or Teflon (registered trademark) can also be used. Titanium and gold are biologically compatible and inert and require no special treatment.

In Fig. 2 it is shown that the stent 1 is centrally located and positioned with respect to the length of balloon 5 and that the turns of the flat preformed wire band 3A are evenly spaced so that when stent 1 is expanded as shown in Fig. 5 and Fig. 6, stent 1 will provide even support inside a vessel 8, and be able to resist external loading.

In Fig. 3 it is shown how balloon and stent assembly 5A emenate from a guiding catheter 9 inside vessel 8 and is advanced towards a partial occlusion 10. In Fig. 4 it is shown how balloon and stent assembly 5A are located inside occlusion 10 within artery 8, balloon 5 still being deflated. Once positively placed within occulsion 10, balloon 5 is inflated using standard angioplasty procedures and techniques. As balloon 5 expands, so does the stent 1 as shown in Fig. 5. The expanding balloon 5 together with stent 1 compresses the plaque 7, said plaque remains compressed and stent 1 retains said plaque 7 and prevents possible reocclusion. Angioplasty procedure completed, balloon 5 is deflated and withdrawn leaving stent 1 firmly implanted within vessel 8. Previously occluded vessel 8 is now completely recannalized and patency is restored.

Fig. 6 shows stent 1 firmly implanted and imbedded in compressed plaque 7, providing both adequate support as well as a smooth lumen void of all protrusions, a very desirable feature and condition, since any protrusions are conducive to turbulant blood flow and potentiol formation of thrombosis.

To test the viability of this novel principle of stent construction a polyester-coated copper wire of 0.2 mm (.008") diameter was preformed into a zig-zag pattern 3 as shown in Fig. 1 to form a band 3A. This band was subsequently wound into a tubular shape with ends curled into tight loops 2A to prevent sharp ends of wire 2 from perforating balloon 5. The tubular stent 1 was placed over a 3.5 mm PTCA 20/3.5T balloon made by SciMed and fitted tightly over said balloon. The balloon and stent assembly 5A was fed through an 8F guiding catheter into a silastic thin-wall tubing approx.3 mm inside diameter and the balloon was inflated with a standard 10 cm^3 syringe using plain water. The expansion of the stent was observed and documented on video. Several subsequent tests of similar nature also using larger balloons typically MeadoxSurgimed A/S Cat. No. 700720 10 mmdia. and Medi.tech balloon 12 mm dia. were used with a stent made of polyester-coated copper wire 0.36 mm (.014") dia. All tests showed near-perfect expansion and "bench-type" implantations. Further experiments showed that multiple stents can be used in tandem. In fact, a typical balloon and stent assembly can be fed right through a previously implanted and expanded stent and be implanted downstream ahead of the previously implanted stent, a distinct advantage in real life situations.

Experimental laboratory tests on animals are now being conducted. Initial results are very encouraging and promising.

Both intracoronary and intraaortic stents are being investigated at this time, a complete protocol is being prepared.

Five stents recently implanted in small arteries of pigs and expanded to 3.5 mm have successfully maintained 100 % patency for several weeks and as of this date continue to do so.

In a separate experiment, a previously created aortic dissection has been stopped by expanding a 10 mm diameter stent within said dissection.

Claims

1. A radially expandable vascular stent of the type formed of wire (2) wound generally in a helix, characterized by bends (3) in the wire (2) outside its helical path which straightens as the stent (1) is expanded.

2. A stent as defined in claim 1 wherein the bends (3) define a continuous wire formed flat band (3A).

3. A stent as defined in claim 2 wherein said flat band (3A) is wound on the flat into said helix.

4. A stent as defined in any one of the preceding claims wherein the bends are defined by a zig-zag pattern (3).

5. A stent as defined in claim 4 wherein the zig-zag pattern (3) is oriented longitudinally with respect to the axis.

6. A stent as defined in any one of the preceding claims wherein the helix is of cylindrical shape.

7. A stent as defined in any one of the preceding claims wherein both ends of the wire (2) are curled into loops (2A).

8. A stent as defined in any one of the preceding claims wherein the wire wound helix has the low memory level of a softer than spring type metal used for the wire (2).

9. A stent as defined in any one of the preceding claims wherein the wire (2) is made of a copper alloy.

10. A stent as defined in any one of claims 1 to 8 wherein the wire is made of surgical grade stainless steel.

11. A stent as defined in any one of claims 1 to 8 wherein the wire (2) is made of biologically compatible titanium.

12. A stent as defined in any one of claims 1 to 8 wherein the wire (2) is made of gold having a purity of at least 18 K.

13. A sent as defined in any one of the preceding claims wherein the unexpanded stent (1) has an outside diameter equal to or less than 1.9 mm (.075 inch).

14. A stent as defined in any one of the preceding claims wherein the stent (1) is radially expandable to approximately three times its original diameter.

15. A stent as defined in any one of the preceding claims in combination with means (5) within the wire winding for expanding the winding.

16. A stent as defined in claim 15 wherein said expanding means is an expandable balloon (5) extending longitudinally within the winding.

17. A stent as defined in claim 16 wherein the preformed wire winding is tightly fitted and sized to firmly grip the balloon (5).

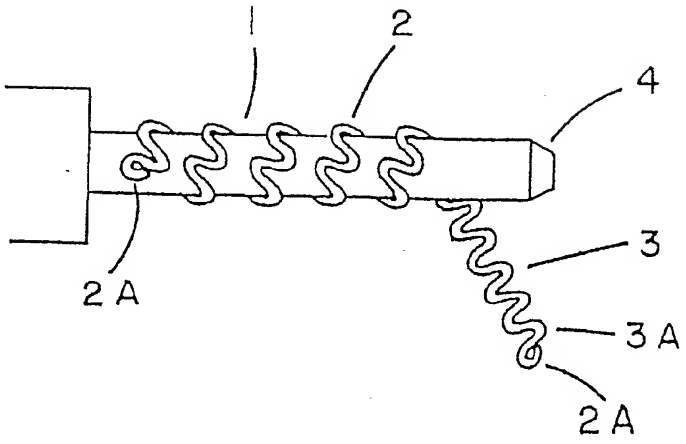

FIG. 1

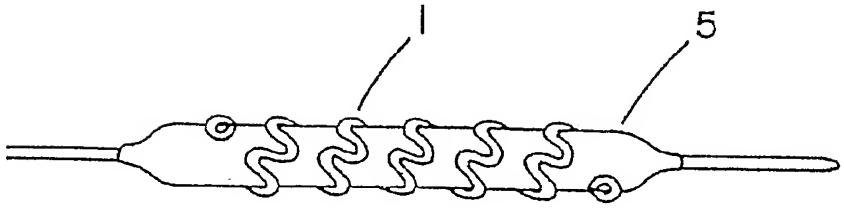

FIG. 2

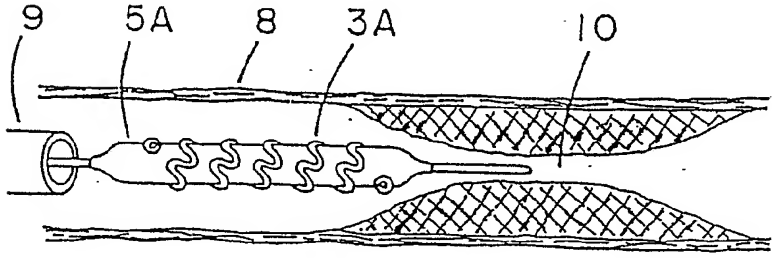

FIG. 3

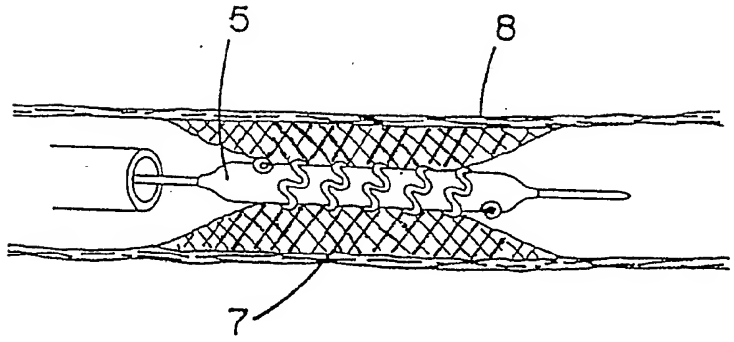

FIG. 4

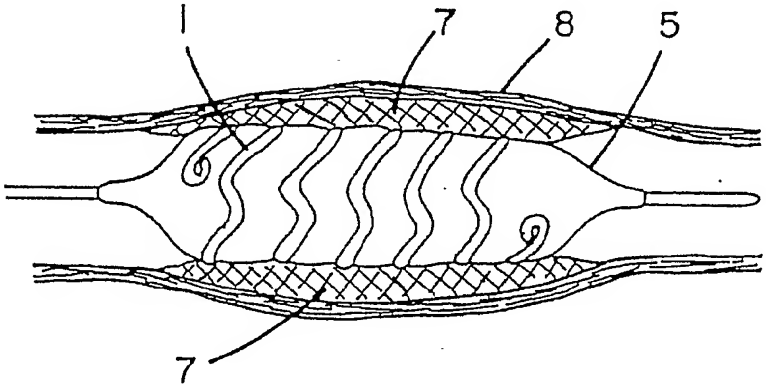

FIG. 5

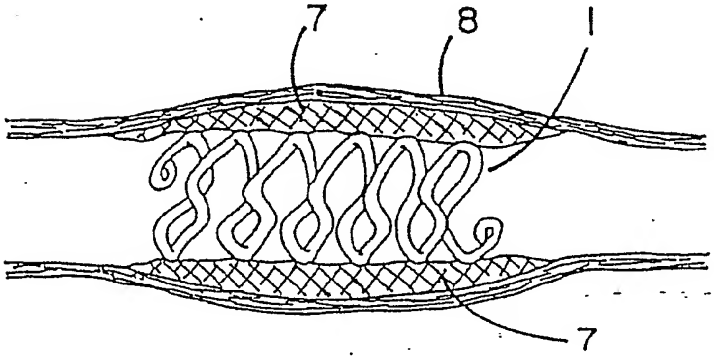

FIG. 6

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 88 11 6594

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
D,A	US-A-4 553 545 (MAASS et al.) * figures 22,23; column 12, lines 52-56 * ---	1	A 61 F 2/06
D,A	US-A-3 868 956 (ALFIDI et al.) * claims 1,24; figures 11,12 * ---	1	
A	FR-A-2 525 896 (WALLSTEN) * claims 1,11; figures 1,2 * -----	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 F 2/00
A 61 M 29/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	17-01-1989	KANAL P K

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
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D : document cited in the application
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